Message

From: Matthias Herzler [Matthias.Herzler@bfr.bund.de]
Sent: 3/15/2018 8:13:02 AM
To: Derek.KNIGHT@echa.europa.eu
Subject: Antw: RE: EU-ToxRisk RAB: Date for 1st TelCo and draft case study documentation guidance
Attachments: IMAGE.jpeg

Dear Derek,

thank you very much for this comprehensive feedback! I think your considerations are indeed very valid.

Specifically I agree that section 3.2 of the document could be more specific as to which template to use for which purpose. The sentence I have there at the moment ("Since every EU-ToxRisk case study is different, there can be no general recommendation which of these templates should be used for which case"), while true, is of course more of a placeholder than what in German we would call "wisdom's final conclusion",

In addition I appreciate your suggestion on how case studies should be written. However, my problem currently is that I do not have a clear picture of how far-reaching our RAB mandate can or even should be. In my view we can give generic advice but cannot get too specific about individual case studies, but that of course would be subject to discussion. Also it is just a feeling (and perhaps a wrong one), but while the project core team seems to be genuinely committed to these issues, case study leaders - while accepting the need for regulatory impact in general - seemed slightly less enthusiastic about people telling them how to do their work.

On the other hand I also understand we still have regulatory case study supervisors in place (I used to be one, but for the case study which has been terminated now)? Having much more intimate knwoledge of the individual case study details, maybe these people are in a better position to suggest the way in which they should be reported (both content- and processwise).

So a practical solution could be to assure that all regulatory case study supervisors are part of the RAB, and that the former play a decisive role in implementing the more generic recommendations of the latter.

Anyway I understand we will not have a problem to fill the 90 minutes of next week's teleconference...

Kind regards,

Matthias

PS: Would you mind if I shared this conversation with the group? It would give them the chance of considering your suggestions already in advance of the telco.

Dr. Matthias Herzler
-
German Federal Institute for Risk Assessment
Unit Chemicals Safety
Department Chemical and Product Safety
-
Max-Dohrn-Str. 8-10, 10589 Berlin, Germany

Tel. +49 30 18412 4402
Fax +49 30 18412 64402
www.bfr.bund.de
matthias.herzler@bfr.bund.de

>>> KNIGHT Derek <Derek.KNIGHT@echa.europa.eu> 14.03.2018 18:34 >>>
Dear Matthias,

I confirm I will attend the TC meeting of the RAB on 22/3/18.

Many thanks for this excellent draft of the RAB recommendations on how to document case studies for regulatory evaluation. It is very comprehensive in listing all the relevant guidance & templates for chemicals, but note I have not (yet) looked at it from the perspective of biocides. As you note below it could be extended to cover other legislations, notably from EMA & EFSA. I like the way you have highlighted the most important information by grey shading.

I am a bit concerned whether there will be adequate resource, time & expertise to write up the NAM-enhanced read-across case studies. The SAB has previously suggested EU-ToxRisk engage experienced regulatory toxicologist consultants to do this. I am also concerned that there is no agreed common format for the case study reporting. At the GA I understood that this will be based on ECHA's RAAF, but it is not clear how this will be applied. In my view approach would be to write the read-across justification based on the RAAF first without the NAM evidence, to identify knowledge gaps for the particular case, then to write a second version with the added NAM evidence, which would include a discussion of the improvement in the confidence of the read-across justification & also the remaining gaps with suggestions of further research to fill these. This approach was successfully tried out in the three NAM-enhanced read-across case studies in ECHA's April 2016 NAM TSWS. I think there are three levels of detail necessary for the reports: (a) the individual NAM test results, (b) combining mechanistic evidence for each AF in the RAAF & (c) the final combination of the evidence to give the overall conclusion on the read-across justification. Perhaps the RAB recommendations on how to document case studies for regulatory evaluation should highlight which guidance/template can be used for each of these stages. I suggest that it is essential to report the case studies taking into account their purpose: i.e. (i) to enable each case study to be examined from the regulatory perspective and (ii) with a view to drawing general conclusions drawn from the set of case studies that can be used for the NAM-enhanced read-across guidance.

I hope these remarks are useful.

Best wishes from,

Dr Derek J Knight
Senior Scientific Officer
Evaluation Directorate
European Chemicals Agency
Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland
Tel. + 358 9 6861 8215
derek.knight@echa.europa.eu
echa.europa.eu

From: Matthias Herzler [mailto:Matthias.Herzler@bfr.bund.de]
Sent: 12 March 2018 11:12
To: Dominique.MASSET@ansm.sante.fr; dobrev.ivan@baua.bund.de; bodo.haas@bfarm.de; Elke.Roehrdanz@bfarm.de; Bernauer Ulrike <Ulrike.Bernauer@bfr.bund.de>; jw.vd.laan@cbg-meb.nl; la.v.aerts@cbg-meb.nl; KNIGHT Derek <Derek.KNIGHT@echa.europa.eu>; Andrea.TERRON@efsa.europa.eu; Georges.Kass@efsa.europa.eu;

JUDSON.RICHARD@EPA.GOV; thomas.russell@epa.gov; Karen.DavisBruno@fda.hhs.gov; Sandra.Kweder@fda.hhs.gov; suzanne.fitzpatrick@fda.hhs.gov; weida.tong@fda.hhs.gov; paules@niehs.nih.gov; Magdalini.SACHANA@oecd.org; emiel.rorije@rivm.nl; joop.de.knecht@rivm.nl; lidka.maslankiewicz@rivm.nl; martin.paparella@umweltbundesamt.at; Vera.Rogiers@vub.be
Cc: thomas.steger-hartmann@bayer.com; Tralau Tewes <Tewes.Tralau@bfr.bund.de>; r.graepel@lacdr.leidenuniv.nl; suhou@mst.dk
Subject: EU-ToxRisk RAB: Date for 1st TelCo and draft case study documentation guidance

Dear colleagues,

thank you for taking part in the Doodle poll. As expected, given the size of our group, we will not find a date which suits everybody. I have decided that we will hold our first teleconference on

Thursday, March 22 from 15-16.30 h CET which should translate into 9-10.30 h EST

(North American colleagues please cross-check). Please save the date. I will talk to the EU-ToxRisk secretariat whether they will be able to organise a webconference or whether this will be a teleconference only and get back to you as soon as I know. The tentative agenda looks something like this (please feel free to suggest any modifications):

1. Round of mutual introduction

2. Short discussion on the role and mandate of the group

3. Discussion of the document containing our recommendations for documentation of the case studies.

With this email (apologies for the slight delay) I am sending you the first draft of this document, as announced in my previous email. Apologies for the slight delay. Don't be shocked by the number of pages, the recommendation text itself (i.e. sections 1-3) is only 3.5 pages long.

Since so far this text represents only my view (which is strongly shaped by working under data-rich regulations such as PPP, BPD, REACH, and CLP), please feel free to comment, add (in particular views from other legislations), or tear apart as you wish (but please use tracking mode for this purpose). I am sure it can still be much improved! However, since some people have already started writing up their case studies, it would be important that we conclude on this pretty soon. By this I mean that, ideally any major comments would have reached me before our TelCo and could already be discussed there. On the other hand, I understand this is rather short notice.

4. AOB

Thanks, and best regards,

Matthias

Dr. Matthias Herzler
-
German Federal Institute for Risk Assessment
Unit Chemicals Safety
Department Chemical and Product Safety
-
Max-Dohrn-Str. 8-10, 10589 Berlin, Germany

Tel. +49 30 18412 4402
Fax +49 30 18412 64402
www.bfr.bund.de
matthias.herzler@bfr.bund.de